Additional Questions and Answers to RFP NIH-NIAID-DMID-PR2004-01
'Neutralizing Monoclonal Antibodies Type A for Botulinum Neurotoxins'
Q&A 14 - 16

Q 14. Is it a definite prerequisite that the three antibodies are supplied as separate antibody compositions, or will the following principle also qualify (provided that adequate CMC data is supplied): One protein composition which consists of a mixture of the three antibodies (total protein amount 21 gram) and which has been manufactured under GMP from an oligoclonal working cell bank.

Answer: If multiple antibodies are being proposed, they should be supplied as separate antibody compositions. The cGMP material is needed for proof-of-principle preclinical and clinical evaluation, for which some testing may require the evaluation of individual components or custom blending of individual components.

Q 15. In the event that the contractor encounters a delay beyond its control in obtaining the monoclonal antibodies from the University of California, or any other delay outside the contractor's control, will the contractor be entitled to request an equitable adjustment to the schedule, consistent with the "Changes" clause?

Answer: Part of the evaluative criteria for each applicant is their documented and timely access to the starting materials and their ability to meet the deliverables within the specified period of time. Stated in the RFP, Offerors are to base their technical proposal on an estimated maximum total budget of $15M.

Q 16. The organization's annual report is great than 50 pages, longer than the allocated number of pages for the business proposal. Do you require just financial statements (balance sheet, income statement, Statement of Cash Flows) or the entire 10K as filed with the SEC? Similarly, is a summary of the official travel policy adequate?

Answer: The 50-page limit **applies** to both technical and business proposals. However, the Representations and Certifications and the Financial report which includes travel policies are excluded from the 50-page limitation.